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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,054	08/30/2001	Seiichi Araki	0291266.00124US1	8743
23483	7590	03/20/2008	EXAMINER	
WILMERHALE/BOSTON			ANDERSON, JAMES D	
60 STATE STREET			ART UNIT	
BOSTON, MA 02109			PAPER NUMBER	
			1614	
			NOTIFICATION DATE	
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			03/20/2008	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 09/943,054	Applicant(s) ARAKI ET AL.	
	Examiner JAMES D. ANDERSON	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-6,8,9 and 58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6,8,9 and 58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/420,632.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input checked="" type="checkbox"/> Other: <u>Blank PTO/SB/51 (10-05) Forms</u> . |

DETAILED ACTION

Claims 1, 3-6, 8-9, & 58 are presented for examination

Applicants' amendment filed 1/9/2008 has been received and entered into the application. Accordingly, claims 1, 3-6, 8 and 9 have been amended and claims 59-62 have been cancelled.

The amendments and Applicants' remarks have overcome the rejections not reiterated herein from the previous office action. Such rejections are hereby withdrawn. The following rejections are either reiterated or newly applied and constitute the totality of issues remaining in the present application.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
It was not executed in accordance with either 37 CFR 1.66 or 1.68.

Additionally, the foreign priority data required to establish a proper claim to a prior-filed foreign application is missing from the oath/declaration. Attached, please find form PTO/SB/51 (10-05) which contains all of the required information. Note the checkbox for claiming foreign priority under 35 U.S.C. 119. While applicants do not have to use the attached forms, a new oath or declaration must have all the information in the PTO-SB-51 (10-05) form.

Defective Oath

The reissue oath/declaration filed 1/9/2008 is defective (see 37 CFR § 1.175 and MPEP § 1414) because of the following: the substitute oath/declaration is not signed by all of the inventors and is thus defective as noted above. The Examiner acknowledges that Applicants indicated in their response filed 1/9/2008 that the signatures of the inventors are currently being obtained. However, as of the date of this Office Action, a signed oath/declaration has not been received by the Office.

The original oath/declaration is defective because of the following: 1) the subject matter of amended claims 1, 3-6 and 8-9, drawn to a method of enhancing the immune response to infection by *E. coli*, was not identified as an error in the originally filed oath/declaration; and 2) the subject matter of newly added claim 58, drawn to the method of claim 1 further comprising glutamine and proline, was not identified as an error in the originally filed oath/declaration.

Examiner notes that the errors identified in the oath/declaration are not sufficient to specifically identify errors in the claims. For example, merely stating a "...failure to include a claim directed to..." is not considered a sufficient error statement since Applicants have not pointed out what the other claims lacked that the newly added or amended claims have, or *vice versa*. Please see M.P.E.P. § 1414(II)(C).

A supplemental oath/declaration is required.

Claim Rejections - 35 USC § 251

Claims 1, 3-6, 8-9 and 58 are rejected as being based upon a defective reissue Oath/Declaration under 35 U.S.C. § 251 as set forth above. See 37 CFR § 1.175.

The nature of the defect(s) in the Oath/Declaration is set forth in the discussion above in this Office action.

Claim Rejections - 35 USC § 112 (1st Paragraph)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 3-6, 8, and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a New Matter rejection.

Upon further consideration of the claim amendments submitted 6/1/2007, the amendments to claims 1 and 3 introduce new matter not supported by the originally filed disclosure.

With respect to claim 1, Applicants amended the claim to introduce the limitation "...flavin mononucleotide, flavin adenine dinucleotide, or pharmacologically permissible salts thereof". However, the originally filed disclosure only provides written support for pharmacologically permissible salts of riboflavin, not flavin mononucleotide or flavin adenine dinucleotide as now recited in the instant claims (col. 3, lines 47-51). Accordingly, the pharmacologically permissible salts of flavin mononucleotide and/or flavin adenine dinucleotide recited in claim 1 and claims dependent from claim 1 introduce new matter in the claims.

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With respect to claim 3, Applicants amended the claim to recite an antibiotic “effective against *E. Coli*”. This limitation introduces new matter in the claim because the originally filed disclosure only provides written support for the specific antibiotics amoxicillin, tetracycline, and oxycycline hydrochloride. There is no support in the disclosure for an “antibiotic effective against *E. Coli*” as now recited in claim 3.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES D. ANDERSON whose telephone number is (571)272-9038. The examiner can normally be reached on MON-FRI 9:00 am - 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/James D Anderson/
Examiner, Art Unit 1614

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/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614